



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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5/24/98

PURGED

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

May 14, 1998

WARNING LETTER

cc: HFI-35/FOI Staff
DWA

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 26

Eileen Quinlan
Administrator
Aurora Medical Group--Fond du Lac
210 Wisconsin American Drive
Fond Du Lac, Wisconsin 54935

Dear Ms. Quinlan:

Your mammography facility (MQSA certificate #210328) was inspected on April 30, 1998, by a representative of the State of Wisconsin on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

1. A radiologic technologist, [REDACTED], did not meet the requirement of being licensed by a State or board certified by any of the approved boards.

In addition to the Level 1 condition, several other non-compliances were noted. These include:

Level 2

2. Phantom image test results were not recorded for 4 months:
[REDACTED] Mammo Room.

Page Two

Eileen Quinlan

May 14, 1998

Level 3 Repeats

3. Processor QC; corrective actions for processor (QC) failures were not documented on at least one occasion: [REDACTED] M35 or M35A-M Room Id=Dark Room.

Level 3

4. The MQSA certificate was not properly displayed.
5. Measured darkroom fog exceeded 0.05 (the measured fog level was 0.07): Room=Dark Room.
6. Processor QC: the control limits for the density difference (DD) and/or the mid-density (MD) exceeded ± 0.15 : [REDACTED] M35 or M35A-M Room Id=Dark Room.
7. Documentation was missing from the quality assurance (QA) program. The missing QA items are listed below:
 - Personnel Responsibilities
 - QC Test Procedures

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- * impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- * suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

Page Three

Eileen Quinlan

May 14, 1998

- * seek an injunction in Federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all of the Level 1, 2, and 3-repeat violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the non-compliances that were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted.)

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

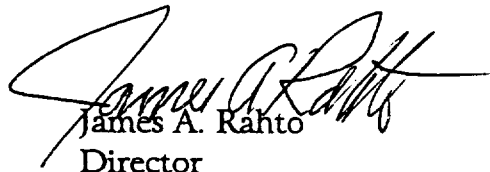
Please send the original copy of your response to Tom Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305. Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

Page Four

Eileen Quinlan
May 14, 1998

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Tom Garvin at (414)771-7167 ext. 12.

Sincerely,

A handwritten signature in black ink, appearing to read "James A. Rahto". The signature is fluid and cursive, with a large initial "J" and "R".

James A. Rahto
Director
Minneapolis District

TWG/ccl

xc: Paul Schmidt
Chief, Radiation Protection Unit
State of Wisconsin
P.O. Box 309
Madison, WI 53701